



Government of the District of Columbia  
Department of Health



State Health Planning and  
Development Agency

May 31, 2013

Kathleen M. Stratton  
Counsel for MedStar Health, Inc.  
Crowell & Moring  
1001 Pennsylvania Avenue, N.W.  
Washington, D.C. 20004-2595



**Re: Establishment of Proton Therapy Services at MedStar Georgetown  
University Hospital - Certificate of Need Registration No. 12-3-9**

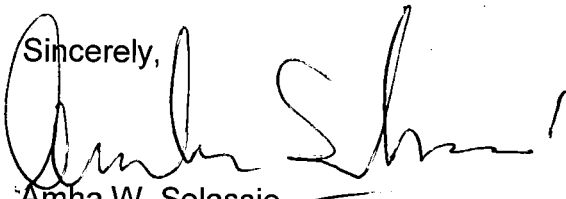
Dear Ms. Stratton:

The D.C. State Health Planning and Development Agency (SHPDA) has approved your application for a Certificate of Need (CON) as referenced above. A statement of findings and the Certificate of Need are enclosed.

Please note that any person may request reconsideration of the review decision within 30 days of this decision. The SHPDA may grant a reconsideration request upon demonstration of "good cause", as defined in D.C. Official Code § 44-412 (b) and Certificate of Need Regulations, 22 DCMR Section 4312.

Thank you very much for your cooperation during the review period. If you have questions concerning this matter, please do not hesitate to contact me.

Sincerely,



Amha W. Selassie  
Director

AS:dIm

Enclosures

cc: Sharon Lewis  
Linda Elam



**Government of the District of Columbia  
Department of Health**



State Health Planning and  
Development Agency

**DISTRICT OF COLUMBIA  
STATE HEALTH PLANNING AND DEVELOPMENT AGENCY  
Notice of Official Action  
Certificate of Need  
Number 12-3-9**

MedStar Health, Inc./MedStar Georgetown University Hospital is hereby awarded this Certificate of Need in conformance with the District of Columbia Certificate of Need statute, D.C. Official Code § 44-401 et. seq. for the establishment of a one-gantry proton therapy service.

This issuance is based on all specifications contained in the Certificate of Need application and related documents in the record. Deviations from the specifications are allowable pursuant to the statute. The capital expenditure associated with this project is \$32,089,000. The State Health Planning and Development Agency herewith makes all findings applicable to this issuance as required by the statute.

The certificate of need is issued contingent on the following conditions:

- Given the incidence and prevalence of cancer in the District of Columbia and given the health disparities in the city, the Applicant shall, in consultation with the Department of Health, establish, operate and maintain a full time new cancer screening and treatment clinic in one of the underserved areas of the District in Ward 5 or 7, particularly to prevent and treat the most common cancers – breast, lung, prostate and colorectal - and provide a clear plan of implementation with its second quarterly progress report;
- In order to ensure that underserved, uninsured, underinsured, and minority patients have access to proton therapy treatment, the Applicant must enter into clear arrangements with the D.C. Primary Care Association, clinics, hospitals, and other entities that serve these patients and establish mechanisms to facilitate access to the proton therapy services and report to the SHPDA with its first year progress report; and

- Provide to SHPDA annually information on the proton therapy utilization and on the operations of the cancer screening and treatment clinic, including the number of patients served, the diagnosis, source of payment, source of referral, as well as the race, age, sex, ward, and zip code of the patients.


This Certificate of Need is valid until May 31, 2016 unless: (1) its issuance is revoked following a public hearing held for reconsideration of this issuance in accordance with DC Official Code § 44-412, or further proceedings in accordance with DC Official Code § 44-403 or 44-414; (2) it is withdrawn in accordance with DC Official Code § 44-411; or (3) it is terminated because the State Health Planning and Development Agency has certified that operations may begin, in accordance with DC Official Code § 44-409.

Unless this Certificate of Need has been revoked, withdrawn, or terminated, quarterly progress reports must be submitted to the State Health Planning and Development Agency on August 31, 2013, November 30, 2013, February 28, 2014, and May 31, 2014. The reports should also be submitted quarterly every year until the project is completed.

Notification of the proposed date for the initiation of operation of the facility or service approved here in should be provided to the State Health Planning and Development Agency no later than thirty days prior to the proposed date for the initiation of operation so that the review required by DC Official Code § 44-409 may be conducted.

Signed this 31<sup>st</sup> day of May, 2013.

Sincerely,



Anna W. Selassie  
Director

AS:dIm



**Government of the District of Columbia  
Department of Health**



State Health Planning and  
Development Agency

**DISTRICT OF COLUMBIA  
STATE HEALTH PLANNING AND DEVELOPMENT AGENCY  
CERTIFICATE OF NEED REVIEW  
FINDINGS IN THE MATTER OF:  
MEDSTAR HEALTH, INC./MEDSTAR GEORGETOWN UNIVERSITY HOSPITAL  
CERTIFICATE OF NEED REGISTRATION NO. 12-3-9**

The findings contained in this document were developed in conformance with Certificate of Need (CON) review criteria required by D.C. Official Code § 44-409, and contained in regulations, 22 DCMR B4050 et. seq. These findings reflect my assessment of the information in the project record, and its consistency with the applicable considerations, standards and criteria for CON review. These findings are based on all specifications contained in the CON application and all related documents and testimony submitted to the record.

The findings take into account the recommendations of both the Project Review Committee (PRC) and the Statewide Health Coordinating Council (SHCC) in their respective deliberations on March 21, 2013, April 18, 2013, and May 16, 2013.

**A. Overview of the Applicant and the Proposed Project:**

MedStar Health, Inc./MedStar Georgetown University Hospital has applied for a certificate of need to establish proton therapy services. MedStar Georgetown University Hospital (MGUH) is a duly licensed and accredited, not-for-profit, acute-care teaching and research hospital with 609 beds, located on Reservoir Road in Northwest Washington. The Applicant maintains that since its founding in 1898, the hospital has been dedicated to promoting health through education, research, and patient care. The Applicant states that Georgetown University sold MGUH to the MedStar Health System

in 2000. MedStar Health is a not-for-profit healthcare organization that operates more than 80 entities, including nine hospitals in Washington, D.C. and Maryland. As the area's largest health system, it is also one of its largest employers, with more than 27,000 associates and 5,600 affiliated physicians. MedStar Health facilities serve more than 1.5 million patients annually.

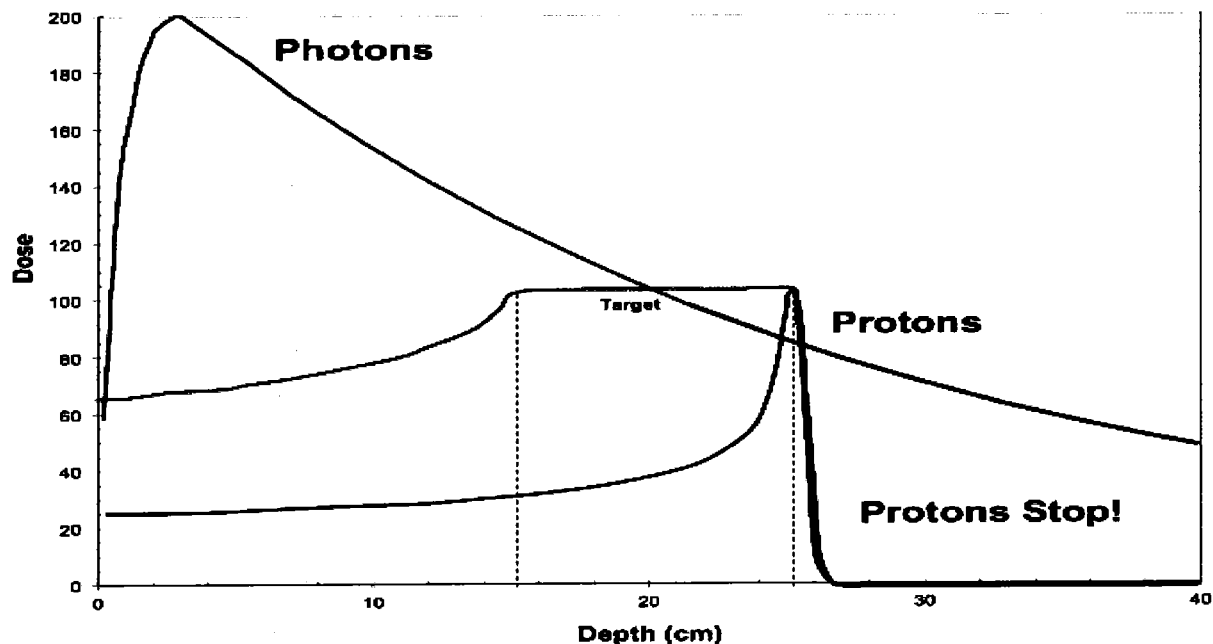
The Applicant maintains that in 1970, Georgetown University authorized the establishment of the Lombardi Comprehensive Cancer Center (LCCC) in honor of Vincent T. Lombardi, former coach of the Green Bay Packers and the Washington Redskins, who was treated for cancer at MGUH. The facility was established with funds from the University, the federal government and private sources. The LCCC became the 16th National Cancer Institute (NCI) designated Comprehensive Cancer Center and is currently one of only 41 NCI-designated comprehensive centers in the country and the only center in the Washington metropolitan area. According to the NCI, an NCI-designated comprehensive cancer center "must demonstrate reasonable depth and breadth of research in each of three major areas: laboratory, clinical, and population-based research, as well as substantial transdisciplinary research that bridges these scientific areas. Additionally, a comprehensive center must also demonstrate professional and public education and outreach capabilities, including the dissemination of clinical and public health advances in the communities it serves." The Applicant further states that Georgetown University's leadership aggressively encourages and supports multi-programmatic and multidisciplinary research, while maintaining a commitment to the highest quality patient care. According to the Applicant, the partnership between Lombardi and MGUH ensures that patients have access to cutting-edge cancer care, provided by dedicated professionals in a supportive and caring setting.

The Applicant is now proposing the establishment of a proton therapy center on the MGUH campus. Proton therapy is a type of particle therapy which uses a beam of protons to irradiate diseased tissue in the treatment of cancer. Proton therapy starts with the injection of hydrogen atoms into an accelerator. Using magnetic fields, the

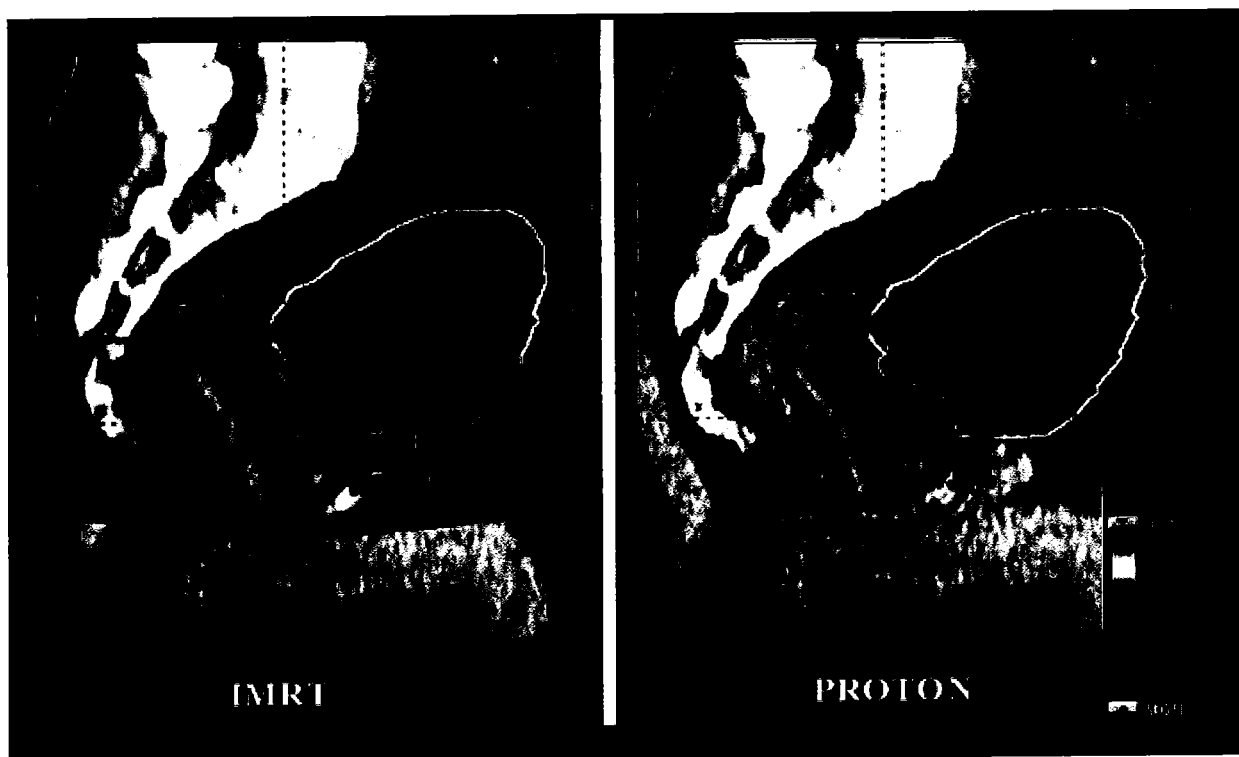
atoms are accelerated in a circular motion. During this time, the hydrogen atoms shed their electrons, leaving behind only positively charged protons. Billions of protons are accelerated to nearly the speed of light, which generates the proton beam. The proton beam is then controlled to treat the patient.

In contrast, photon radiation is generated by the interaction of accelerated electrons and a heavy metal. The linear accelerator speeds up the electrons, and these electrons are directed to strike and interact with a heavy metal target, often tungsten. The result of the interaction is the generation of photon radiation, also called x-ray radiation. X-rays are photons like light and have no mass. However, photon radiation used to treat cancer has energies that are several million times higher than light. Along the way, the photon radiation deposits small amounts of energy or radiation dose that ionizes human tissue in its path. Photon radiation therapy is indiscriminating in causing damage to healthy tissue upstream of the tumor, the tumor, and healthy tissue downstream of the tumor.

The Applicant maintains that proton therapy is one of the most precise and sophisticated forms of external beam radiation therapy available. The advantage of proton radiation therapy over conventional radiation (photon) is its ability to deliver higher doses of shaped beams of radiation directly into the tumor while minimizing the dose to normal tissues. When the protons reach a specific depth, protons deposit a large focused amount of energy and then stop, leaving no energy beyond that depth known as the Bragg Peak. The depth of the Bragg Peak is precisely controlled by changing the energy of the protons, thus allowing physicians to precisely tailor the proton dose to the specific depth and shape of the tumor while greatly reducing the dose to surrounding healthy tissue. As a result, the Applicant maintains that proton therapy leads to reduced side effects and improved survival rates due to its potential for greater accuracy. The following chart demonstrates the Bragg Peak:



According to the Applicant, on a clinical level, proton therapy is anticipated to provide the same if not better benefits as photon therapy. The main advantage of proton therapy is its potential for greater accuracy. Many tumors are located near sensitive tissues and/or other critical organs and structures. Proton therapy represents a treatment option that targets the tumor leaving minimal peripheral tissue damage. The following picture shows the affected tissue in a conventional radiation Intensity-modulated radiation therapy (IMRT) and that of proton therapy.



The Applicant proposes to establish a proton therapy center on the campus of MGUH at the LCCC. The Applicant states that the focus of the proposed proton therapy program will be spine, brain, prostate, lung, head and neck, and gynecology cancers, as well as pancreas, liver, kidney, and colon cancers. The equipment proposed is the Mevion S-250 Proton Radiation Beam Therapy System. The Mevion S-250 is an FDA-approved, relatively low cost, one-room integrated device that is a completely integrated system incorporating all functionality necessary to efficiently treat patients. The Applicant states that the proton system requires a three-story concrete lined building with a treatment room and walkway above and below the treatment room for accessing the proton arm for servicing. Additionally, there will be a room to house the equipment controls, a patient staging area, and a computer console area at which physicists, physicians, and technicians will monitor the patient treatment.

The Applicant states that the Mevion S-250 clinical environment has been designed to operate similar to current linear particle accelerators as a fully integrated system with accurate patient positioning and imaging. All systems are controlled by a three-tiered



control architecture with complete integration of oncology information systems to support scheduling, verification, and recording of treatments. A six degree robotic couch moves the target to its treatment position with sub-millimeter accuracy and the 2D/3D radiographic imaging system is used to accurately confirm patient position and apply final alignment corrections. Once the patient is in position, the dedicated TriNiobium Core power source delivers the beam on demand with no waiting for beam access. The following picture depicts what the Mevion 250 system looks like:



The proposed capital expenditure for this project is \$32,089,000 and the project is scheduled to be completed in 2014. The Applicant states that the proton therapy center will be constructed as an addition to the existing LCCC. The facility will be designed, engineered and constructed by Architection, which has over twenty years of experience in radiation oncology facility development. The project will consist of:

1. A 2,675 square feet, three-level cast-in-place concrete vault addition for the Mevion Proton Therapy System;
2. Construction of a new entrance/lobby/drop-off canopy to the front of the LCCC facility; and

3. Interior renovation of approximately 6,000 square feet for the new proton therapy clinical office suite inside the LCCC facility.

According to the Applicant, the MedStar Health Cancer Network combines the strengths of clinical care and academic research, in order to provide patients with greater and convenient access to comprehensive cancer care and clinical trials. The Network is comprised of four MedStar Health hospitals:

- MGUH's LCCC, the metropolitan area's only NCI Comprehensive Cancer Center
- MedStar Montgomery Medical Center
- MedStar St. Mary's Hospital
- MedStar Washington Hospital Center

The Applicant states that the goals of the MedStar Health Cancer Network are to coordinate cancer services for patients at MedStar's Washington-region hospitals, to significantly expand and support the important research and clinical trials embedded within Georgetown's LCCC, as well as to extend the magnitude and reach of oncologic services. The Applicant maintains that MedStar Health's multi-disciplinary approach to cancer care and research provides the highest level of care for patients and results in better outcomes.

The Applicant reports that the principal objectives of the proton project are to:

- Increase the clinical service capabilities of the Georgetown Department of Radiation Medicine and the LCCC by providing access for Washington metropolitan area residents to advanced cancer therapies;
- Improve and build on MGUH's existing expertise in stereotactic radiosurgery and maximize the synergies and efficiencies of existing programs and clinical infrastructure;

- Advance knowledge about proton therapy through research and provide for the training of future physicians, nurses, physicists, and technical students in these lifesaving procedures; and
- Educate the local medical community and residents of the availability and benefits of proton therapy as a treatment option and to provide access to this lifesaving procedure at the LCCC.

## **B. Review Findings and Conclusion**

### **1. Need for the Proposed Project:**

The Applicant states that the LCCC is the only NCI-designated cancer center in the D.C. metropolitan area and MGUH is also the only academic medical center and research institution in the metropolitan area that operates a dedicated cancer treatment center. The Applicant reports that the LCCC treats over 40,000 cancer patients a year, performing 2,000 cancer surgeries, provides over 50,000 chemotherapy treatments and over 10,000 radiation therapy procedures. MGUH is committed to training its clinicians on the most current, state-of-the-art technology available as evident in that MGUH has one of the highest stereotactic radiosurgery procedure (CyberKnife) volumes of any center in the country. The Applicant maintains that MGUH prides itself on offering the most innovative modalities for the treatment of its patients, the education of its students, and the ongoing training of its clinical staff. The addition of proton therapy to MGUH's radiation service will continue to build on MGUH's existing platform of advanced therapies for the treatment of complex cancers.

According to the Applicant, the treatment of cancer is built on: surgery, medication and irradiation. Cancer patients receive multiple treatment modalities throughout the course of their treatment. However, specific tumor types often dictate the type of treatment, and in the United States, 50-60% of cancer patients receive radiation as part of their cancer care. The Applicant adds that throughout the past 20 years, radiation oncology has grown not only in the number of providers and facilities, but also with respect to its

clinical application and scientific understanding. According to the Applicant, the following points demonstrate the impact of radiation therapy:

- Nearly two-thirds of all cancer patients will receive radiation therapy during their illness;
- The number of radiation oncologists in the U.S. has been growing steadily;
- Over one million patients are treated with radiation therapy in the U.S. every year;
- Three cancers — breast cancer, prostate cancer and lung cancer — make up more than half (56 percent) of all patients receiving radiation therapy;
- For most cancer types treated with radiation therapy, at least 75 percent of the patients are treated with the intent to cure the cancer, rather than control the growth or relieve symptoms like pain. For lung and brain cancers, that number is somewhat lower, with 59 percent of lung cancer patients and 50 percent of brain cancer patients being treated with the goal of curing the cancer;
- An average linear accelerator is used for 4,500 to 6,500 treatments per year. The average patient receiving external beam radiation therapy receives 29 treatments; and
- The average radiation oncologist sees between 200 and 300 patients annually.

The Applicant states that MGUH is the only academic medical center and research institution in the metropolitan area that operates a dedicated cancer treatment center. Additionally, MGUH is the only cancer treatment provider that serves both pediatrics and adults. The Applicant states that proton therapy is especially effective for pediatric tumors in that it can reduce the acute and long-term complications associated with

conventional radiation therapy. The pediatric population is sensitive to the effects of radiation and many of its long-term effects, such as growth abnormalities, second malignancies, neurologic complications, cardiac and pulmonary toxicities, and infertility, which may all be reduced with the use of proton therapy.

The Applicant maintains that MGUH analyzed the service area and population to be served by the proposed proton therapy center at Georgetown and found that there were 1,641 cases of radiation oncology services provided to patients at MGUH/LCCC on an outpatient basis for the 12 month period ending September, 2012. These patients received either conventional radiation therapy services or Cyber Knife services at MGUH/LCCC. The Applicant states that these patients were reviewed by a clinically experienced radiation oncologist: Anatoly Dritschilo, MD, FACR. Dr. Dritschilo first determined that 1,253 radiation oncology cases at MGUH/LCCC included nine tumor site categories for which proton therapy is a potentially beneficial therapy. Based on Dr. Dritshilo's expert clinical judgment, the Applicant projects that 308 patients would have been recommended for proton therapy. The following chart shows the breakdown of the estimates:

Tumor Type	Radiation Oncology Patients	Estimate of Proton Therapy Patients	Average number of Proton Treatments per Patient	Estimated Proton Therapy Treatments
Spine	65	45	20	900
Prostate	346	110	40	4,400
Brain	127	36	30	1,080
Lung	149	30	30	900
Head & Neck	346	35	15	525
Pancreas	70	13	15	195
Liver/Kidney	49	13	15	195
Colon	48	14	15	210
GYN	53	12	20	240
<b>Total</b>	<b>1,253</b>	<b>308</b>		<b>8,645</b>

According to the Applicant, out of the 1,641 cancer patients who were treated at MGUH for radiation oncology services on an outpatient basis, 402 (24%) were residents of the District of Columbia, 708 (43%) were residents of Maryland, 403 (24%) were residents of Virginia, and 128 (9%) were residents of other areas. The Applicant maintains that based on National Cancer Institute data, the incidence rate for all cancers in the Washington metropolitan region is 419.7 per 100,000 or approximately 25,000 new cancer cases in 2011. The following chart shows the estimated cancer rate for the Washington metropolitan region:

<b>Jurisdiction</b>	<b>2011 Population</b>	<b>NCI Cancer Rate</b>	<b>Estimated Cancer Incidence</b>
DC	571,822	447.5	2,559
Prince George's	871,233	408.1	3,556
Montgomery	989,794	406.7	4,025
Charles	149,130	431.5	643
Howard	293,142	432.5	1,268
St. Mary's	107,484	466.5	501
Calvert	89,256	474	426
Anna Arundel	544,403	483.5	2,632
Alexandria City	144,301	344.7	497
Arlington	216,004	372.8	805
Manassas City	39,300	385.7	152
Fairfax City	22,549	385.9	87
Falls Church City	12,751	391.9	50
Fairfax	1,100,692	402.5	4,430
Loudoun	325,405	408.9	1,331
Fauquier	66,071	420.6	278
Prince William	419,006	426.7	1,788
<b>Total</b>	<b>5,962,343</b>		<b>25,026</b>

Source: National Cancer Institute; US Census, 2011 Estimates

The Applicant projects that only a small percentage of patients who might be amenable to proton therapy will actually be directed to this modality by their physicians. The

Applicant state that while it is theoretically possible to 1) identify a service area and its population, 2) apply commonly-accepted cancer incidence rates, and 3) identify the number of persons with the types of cancer amenable to proton therapy, the challenge is projecting actual utilization. Each cancer treatment decision is based on numerous factors related to a particular patient's status and the clinical decision-making of the patient's physicians. These may include: 1) disease site specific information, 2) clinical presentation, 3) alternative available modalities, 4) potential cure rates, 5) quality of life expectations, 6) cost, and 7) evidence of effectiveness of proton therapy.

MGUH analyzed the proton therapy facilities in the United States and found that the actual utilization is well lower than the number of patients that may be amenable to proton therapy. There were 10 proton therapy facilities in operation in the country at the end of 2011 and the following chart depicts their utilization rate:

State	Name of Center	Year of Initiation	Total Patients	Average Annual Patients	Number of Treatment Rooms	Average Annual Pts./Room
California	UCSF-CNL	1994	1,391	82	N/A	N/A
California	Loma Linda	1990	16,000	762	5	152
Indiana	IU Health	2004	1,431	204	4	51
Massachusetts	Boston NPTC	2001	5,562	556	3	185
Texas	MD Anderson	2006	3,400	680	4	170
Florida	UFPTI	2006	3,461	692	4	173
Oklahoma	ProCure PTI	2009	623	312	6	52
Pennsylvania	Upenn	2010	433	433	5	87
Illinois	CDH	2010	367	367	3	122
Virginia	HUPTI	2010	N/A	N/A	5	N/A
Missouri	Siteman Cancer Ctr.	2012	N/A	N/A	1	N/A

The Applicant states that it took a more cautious and conservative approach in analyzing the need for its proton center in order to avoid over projecting future patient

demand and building unnecessary and costly treatment capacity. The Applicant adds that MGUH has taken many factors into account in its service planning, and determined that when and if additional treatment capacity is necessary, it will apply for an expansion of services.

The Applicant maintains that the capacity of the proposed proton therapy program at MGUH is estimated to be 10,500 treatments per year, based on the following:

- 3 patients/hour
- Twenty minutes/treatment
- 14 hours of treatment time/day
- 5 day/week operations
- 50 weeks of operations/year (to account for holidays).

The Applicant projects that on average 28 treatments are required for each patient based on the expected mix of tumor types eligible for proton treatment. The Applicant also projects that based on current patients at MGUH, 308 patients may be eligible for proton therapy, utilizing approximately 82% of the unit's total capacity.

In conclusion, the Applicant maintains that the MGUH proton therapy center will:

- be located in the only academic medical center and research institution in the metropolitan area that operates a dedicated cancer treatment center;
- serve approximately 19% (308/ 1,641) of the cancer patients currently being treated on an outpatient basis for radiation oncology at MGUH;
- treat primarily patients that reside in the Washington metropolitan region; and
- provide a precise form of radiotherapy, to deliver high doses of radiation into a tumor while minimizing the dose to normal tissues.



The Applicant states that a review of independent scientific literature for proton therapy shows that there are no definitive randomized, controlled clinical trials that provide data that demonstrate that proton therapy is more clinically effective than conventional radiation. The Applicant states that “[e]xperts at NCI, specifically, Dr. C. Norman Coleman, Head, Experimental Therapeutics Section, NIH, points out that there is a lack of published randomized controlled trials to show that proton therapy works better than standard radiation therapy at increasing survival or improving quality of life for patients. Solid clinical and long-term evidence that proton therapy is superior is not currently available and will need to be prospectively obtained”.

However, the Applicant maintains that the foundation motivating technical advances in radiation oncology typically have been based on enhancements in the quality of dose distributions, as evaluated by radiation oncologists, both within the tumor volume and nearby critical organs. The Applicant has provided a number of studies that indicate the usefulness of proton therapy for various tumors. These studies include evaluations of head & neck, spine, ocular, gastrointestinal, lung, prostate, bone & soft tissue, and pediatric cancers. The following is a summary of the studies:

### **Head/Neck**

“Proton beam therapy for chordoma and chondrosarcoma is known to be one of the best options to decrease the probability of recurrence after surgical removal. Excellent local control and survival rates have been reported from the United States and Europe from 1989 to 2001. The treatment targets in these reports consisted of the clinical target volume with addition of a significant margin to the remnant tumor. Because microscopic tumor cells around the tumor need to be treated in the postoperative setting, this expanded treatment target volume is large and irregular in shape and frequently involves the critical organs at the skull base (i.e., central nervous system, sensory organs, and cranial nerves). Nevertheless, the prescribed doses are markedly higher than the dose constraints for the critical organs. Proton beam therapy is considered the ideal method for dose-gradient irradiation to irregular-shaped targets among critical organs. Even though the number of subjects was small, the inclusion of larger tumors in

the present study, as compared with that in previous reports of proton beam therapy, with adequate 3-year disease control rates lends support to the concept of use of proton beam therapy for the disease”.

Study found in **PubMed Central Canada** - Fuji H et al. Feasibility of proton beam therapy for chordoma and chondrosarcoma of the skull base. Skull Base. 2011 May;21(3):201-6.

### **Spine**

“Over the past decades, we have witnessed a revolution in the application of photon radiotherapy. Rapid advancements in computer software as well as hardware have resulted in fractionated stereotactic radiotherapy (intensity- modulated radiation therapy) and LINAC-based radiosurgery. Thus, the ability to deliver a conformal photon radiation dose has greatly improved. In addition, indications for GKS have been expanded to include use in malignant skull base lesions. For small tumors with some distance from normal critical structures, there appears to be little difference between high-dose isodose target coverage between three-dimensional conformal photons and similar proton techniques. However, in larger lesions in immediate proximity to normal critical structures and in highly irregularly shaped tumors, proton radiotherapy has consistently been demonstrated, in comparisons with other modalities in terms of target planning and delivery, to maintain an advantage. The fact remains that proton irradiation does not have an exit dose. Therefore, the integral volume of normal tissues receiving radiation will always be smaller compared with that when using photons. This is of particular importance in the pediatric patient in whom even small to moderate amounts of radiation can lead to major cosmetic and life-long functional impairments.”

Study found in US National Library of Medicine National Institutes of Health - J. E. Munzenrider, N. J. Liebsch, Proton radiotherapy for tumors of the skull base, Strahlenther. Onkol. 175, 57-63 (1999)

### **Ocular**

“In conclusion, evidence-based risk score estimates derived from results analysis in a large series of patients predict specific outcomes in individual patients or in defined

groups of patients. This ability can aid in treatment decisions for individual patients and in designing clinical trials. The results show that proton irradiation is highly successful in achieving local control of intraocular melanomas. Vision-threatening complications, including radiation maculopathy and papillopathy, are common in these patients because the tumors arise in proximity to the macula and optic nerve. However, many patients maintain some degree of function in the eye for long periods after treatment. Overall rates of metastatic disease are comparable to those observed after enucleation; thus, enucleation should be limited to patients with large tumors in whom the eye is unlikely to be salvaged by irradiation.”

Study found in the Journal of American Medical Association Ophthalmology - Gragoudas et al, Evidence-based estimates of outcomes in patients treated for intraocular melenoma", Arch. Ophthalmol.120, 1665-1671 (2002)

### **Gastrointestinal**

“All proton plans met all normal tissue constraints and were isoeffective with the corresponding IMRT plans in terms of PTV coverage. The proton plans offered significantly reduced normal-tissue exposure over the IMRT plans with respect to the following: median small bowel V20 Gy, 15.4% with protons versus 47.0% with IMRT ( $p = 0.0156$ ); median gastric V20 Gy, 2.3% with protons versus 20.0% with IMRT ( $p = 0.0313$ ); and median right kidney V18 Gy, 27.3% with protons versus 50.5% with IMRT ( $p = 0.0156$ ). By reducing small bowel and stomach exposure, protons have the potential to reduce the acute and late toxicities of postoperative chemoradiation in this setting.”

Study found in US National Library of Medicine National Institutes of Health - Nichols RC Jr, et al. Protons offer reduced normal-tissue exposure for patients receiving postoperative radiotherapy for resected pancreatic head cancer. Int J Radiat Oncol Biol Phys. 2012 May 1;83(l): 158-63. Epub 2012 Jan 13

## **Lung**

“Fifteen consecutive patients and 20 tumors were treated with proton [stereotactic body radiation therapy] SBRT to 42 to 50 Gy(relative biological effectiveness) in 3 to 5 fractions between July 2008 and September 2010. Treatments were well tolerated with only one case of grade 2 fatigue, one case of grade 2 dermatitis, three cases of rib fracture (maximum grade 2), and one case of grade 3 pneumonitis in a patient with severe chronic obstructive pulmonary disease. With a median follow-up of 24.1 months, 2-year overall survival and local control rates were 64% (95% confidence limits, 34%-83%) and 100% (83%-100%), respectively. We conclude that proton SBRT is effective and well tolerated in this unfavorable group of patients. Prospective clinical trials testing the utility of proton SBRT in stage I [non-small-cell lung cancer] NSCLC are warranted.”

Study found in US National Library of Medicine National Institutes of Health - Westover KD et al  
Proton SBRT for medically inoperable stage I NSCLC. J Thorac Oncol. 2012 Jun;7(6): 1021-5.

## **Prostate**

“Conformal proton beam radiation therapy of prostate cancer can achieve excellent biochemical freedom-from relapse rates with minimal treatment-related morbidity at the doses reported. Additional studies of dose escalation are under way to define further the role of proton therapy in management of this disease”.

Study found in International Journal of Radiation Oncology - Slater J. D. et al, Proton therapy for prostate cancer; the initial Loma Linda University experience, Int. J. Radiat. Oncol. Biol. Phys 59, 348-352 (2004)

## **Bone/soft tissue**

“High-dose proton RT offers excellent chances of lasting tumor control and survival, with acceptable risks. In this series all small- and medium-sized tumors with no demonstrable brainstem involvement have been controlled; all such patients are alive. Surgical debulking enhanced delivery of full tumoricidal doses, but even patients with large tumors and disease abutting crucial normal structures benefited”.

Study found in US National Library of Medicine National Institutes of Health - Hug E. B. et al:  
Proton radiation therapy for chordomas and chondrosarcomas of the skull base, J. Neurosurgery  
91, 432-439 (1999)

**Pediatric Cancers** “The present study clearly demonstrates the advantage of conformal radiation methods, compared to conventional X-ray treatment, for the treatment of posterior fossa and spinal column in children with medulloblastoma. Of the two conformal treatment methods, protons were found to be superior to IMRT. This approach of using focal radiation, especially in combination with concurrent chemotherapy, is very attractive for treating young children with substantial growth potential”.

Study found in International Journal of Radiation Oncology - St. Clair W. H. et al, Advantage of protons compared to conventional X-ray or IMRT in the treatment of a pediatric patient with medulloblastoma, Int. J. Radiat. Oncol. Biol. Phys.58, 727-734 (2004)

SHPDA staff reviewed demographic information on cancer patients in the District and found that according to the American Cancer Society, 2,950 District residents were diagnosed with and 1,010 died from cancer in 2012. Despite progress, cancer persists as the leading cause of premature (before age 70) death in the District, and as the second most common cause of death overall, regardless of gender or race. In the District, African Americans had either the highest incidence or highest mortality rate for each of the identified cancers. African Americans also were most affected by such issues as lack of access, diagnosis at later stage, inadequate palliative care, and low participation in clinical trials. According to a recent Rand report, black residents in the District were 90% more likely to die from cancer in 2008 than white District residents. Overall, DC has one of the highest cancer mortality rates in the nation, ranking:

- higher than anywhere in the United States for prostate cancer;
- second highest in the nation for breast cancer;
- third highest in the nation for cervical cancer; and
- seventh highest in the nation for all cancers combined.

**Age-Adjusted Incidence Rates by Sex and Race for Cancers Diagnosed in 2009, D.C. Residents  
All Sites**

Race	<u>Male and Female</u>		<u>Male</u>		<u>Female</u>		
	Rate*	Count	Rate	Count	Rate	Count	
All Races	492.7	2,772	575.9	1354	442.2	1,417	2,772
White	423.0	709	425.5	325	440.1	383	
Black	507.5	1,830	627.5	913	432.9	917	

**Age-Adjusted Mortality Rates by Sex and Race for Cancer Deaths Occurred 2009, D.C. Residents  
All Sites**

Race	<u>Male and Female</u>		<u>Male</u>		<u>Female</u>		
	Rate*	Count	Rate	Count	Rate	Count	
All Races	199.6	1,122	258.6	558	164.4	564	1,122
White	151.1	253	187.9	128	129.3	125	
Black	232.2	846	310.8	422	186.6	424	

\* Rates are per 100,000 persons and are age-adjusted to the 2000 U.S. standard  
All races includes White, Black and other races

In addition, staff evaluated a report on proton therapy by the American Society for Radiation Oncologists (ASTRO) which is comprised of nearly 10,000 radiation oncologists, medical physicists, dosimetrists, radiation therapists, radiation oncology nurses and nurse practitioners, biologists, physician assistants and practice administrators, making it the largest radiation oncology organization of its kind. ASTRO routinely evaluates new modalities in radiotherapy and assesses the published evidence to determine recommendations for the society as a whole. ASTRO established a Proton Task Force to review proton therapy and provide a recommendation for the utilization of the technology. Data was reviewed for proton therapy in central nervous system tumors, gastrointestinal malignancies, lung, heads and neck, prostate, and pediatric tumors. The following is a summary of the conclusions of the study by the task force:

### Central Nervous System Tumors

“Proton Beam Therapy has multiple theoretical advantages over photon radiotherapy for Central Nervous System tumors due to the ability of Proton Beam Therapy to deliver high dose radiotherapy with steeper dose gradients to proximal critical structures than can be achieved with photon radiotherapy. Clinical data from Proton Beam Therapy or mixed photon/Proton Beam Therapy for base of skull tumors appear superior to previously published series of conformal photon radiotherapy; however, stereotactic photon radiosurgery may provide a significant dosimetric and clinical advantage to standard conformal radiotherapy techniques. Overall, more clinical data (published clinical trials) are needed to fully establish the role of Proton Beam Therapy in Central Nervous System tumors”.

### Lung

“Proton Beam Therapy has been used in the treatment of stage 1 non-small cell lung cancer although no clear clinical benefit over photon therapy has currently been shown. Data regarding the use of Proton Beam Therapy in other clinical scenarios remain limited and do not provide sufficient evidence to recommend Proton Beam Therapy for lung cancer outside of clinical trials. In addition, unlike in some other disease sites, the issue of organ motion in lung cancer is critical and adds an additional challenge to the use of Proton Beam Therapy”.

### Gastrointestinal

“Proton Beam Therapy is mostly untested in GI malignancies, and the number of patients with GI malignancies who are eligible for Proton Beam Therapy will be very small until indications for its use become clearer. In rectal and gastric cancers there appears to be little role for Proton Beam Therapy. In esophageal and pancreatic cancers there may be a rationale for Proton Beam Therapy, as these are two sites often with localized unresectable disease near critical organs at risk, but almost no clinical data exist. In hepatocellular cancer there appears to be the most data and perhaps promise for Proton Beam Therapy as an alternative to photon based approaches, but

more rigorous study and prospective clinical trials are necessary to define the differences in toxicity and efficacy between protons and photons”.

#### Ocular Melanoma

“Proton Beam Therapy has been shown to be effective in the treatment of large ocular melanomas not approachable via brachytherapy. In the group of intermediate tumors that has been well studied by the Collaborative Ocular Melanoma Study group, there is evidence for efficacy of both Proton Beam Therapy and brachytherapy. Further comparative studies will help select patients for the appropriate therapy”.

#### Prostate Cancer

“Prostate cancer has the most patients treated with Proton Beam Therapy of any other disease site. The outcome is similar to Intensity-modulated radiation therapy however, with no clear advantage from clinical data for either technique in disease control or prevention of late toxicity. This is a site where further head to head clinical trials may be needed to determine the role of Proton Beam Therapy. In addition, careful attention must be paid to the role of dosimetric issues including correction for organ motion in this disease. Based on current data, Proton Beam Therapy is an option for prostate cancer, but no clear benefit over the existing therapy of Intensity-modulated radiation therapy photons has been demonstrated”.

#### Head and Neck

“Proton Beam Therapy has been shown to be well suited to treat targets near critical structures, especially at the base of the skull. Data for sinonasal tumors specifically are encouraging, but further data are needed. However, until Intensity-modulated Proton Beam Therapy is more fully developed and tested, it will be difficult to establish whether Proton Beam Therapy may be equivalent to photon Intensity-modulated radiation therapy in treating full head and neck plans. At this time, further clinical data through prospective clinical trials are needed regarding cases in which the target is the primary volume located near critical structures. Currently, there are insufficient data to



recommend Proton Beam Therapy for routine head and neck radiation therapy outside of clinical trials”.

### Pediatrics

“Proton Beam Therapy has perhaps its most developed place in pediatric brain tumors. Although the clinical evidence is lacking, the rationale for using Proton Beam Therapy in posterior fossa tumors, optic pathway tumors, and brainstem lesions is compelling. Future clinical studies reporting on the outcome of patients treated with protons will decide how widespread protons become for pediatric central nervous system tumors. There does not appear to be sufficient evidence at this time to recommend treatment with protons for non- central nervous system pediatric malignancies”.

### ASTRO’s Overall Conclusion

ASTRO concludes that “[c]urrent data do not provide sufficient evidence to recommend Proton Beam Therapy outside of clinical trials in lung cancer, head and neck cancer, GI malignancies (with the exception of HCC) and pediatric non-CNS malignancies. In hepatocellular carcinoma and prostate cancer and [sic] there is evidence for the efficacy of Proton Beam Therapy but no suggestion that it is superior to photon based approaches. In pediatric CNS malignancies there is a suggestion from the literature that Proton Beam Therapy is superior to photon approaches but there is currently insufficient data to support a firm recommendation for Proton Beam Therapy. In the setting of craniospinal irradiation for pediatric patients protons appear to offer a dosimetric benefit over photons but more clinical data are needed. In large ocular melanomas and chordomas, ASTRO believes that there is evidence for a benefit of Proton Beam Therapy over photon approaches. In all fields, however, further clinical trials are needed and should be encouraged.”

To radiation oncologists and physicists, the benefit of proton therapy in terms of science is without question; protons deliver more precise doses of radiation and allow sparing of normal tissue, which is unarguably beneficial to patients. Protons deliver the majority of their energy at a very narrow area within the body. Oncologists can calibrate the Bragg

Peak area to deliver the desired radiation dose to the tumor itself without much entry or exit dose beyond the tumor. It tends to spare the normal, healthy tissues while delivering a more curative dosage.

The overall literature suggests that although there is not clear clinical evidence to demonstrate that at this time proton therapy is better than conventional radiation therapy, the benefits of proton therapy may lead to improved outcomes for specific cancer patients. The potential in proton therapy has not been fully realized and may be the next evolution in cancer treatment. Randomized controlled trials are the only way to solving the questions doctors, researchers, policy makers, insurers, and ultimately patients are asking concerning the quality and efficacy of proton therapy. Therefore, it is important to establish the service at facilities that have the academic, research, and teaching capabilities.

Based on the above, I have concluded that the Applicant has justified the need for the establishment of proton therapy services. The Applicant has demonstrated that radiation oncology continues to grow not only in the number of providers and facilities, but also with respect to its clinical applications and scientific understanding. Proton therapy services will provide an alternative treatment modality for cancer patients. While it is true that the effectiveness of the modality is not definitive, the technology is promising especially for controlling the dose of radiation and minimizing radiation to surrounding tissue and organs. The literature suggests that the modality has the potential to more effectively treat tumors that are close to critical organs and to lead to improved outcomes for specific patients. As an academic, teaching, and research facility, MGUH has also demonstrated the need to establish the services to help train medical students and fellows, as well as to participate in clinical trials and research on the utilization and effectiveness of the modality.

As the staff notes, however, the Applicant does not appear to have taken into consideration the needs of patients from other hospitals in projecting the need for the services. The 308 patients that MGUH projects to serve, based on historical utilization, are primarily to be generated from its patient base. MGUH also states that these

patients will account for over 80% of the unit's capacity. While the Applicant maintains that the District does not need more than one proton facility, it is not clear how other patients, including those in the MedStar Health Cancer Network, will be able to fully access the services. During the Public Hearing the Applicant stated that services may also be provided on Saturdays to add capacity to the facility. Staff notes that based on the Applicant's calculations of 3 treatments an hour, 14 hours a day, 5 days a week, and 50 weeks a year, if an extra day is added then approximately 2,000 treatments or 70 patients could be added to the capacity. SHPDA staff, therefore, believes that the Applicant has not demonstrated that the unit can provide over 12,500 treatments a year, and leaves little room for referrals from other facilities to access the services. This suggests that, based on the need analysis by the Applicant, more than one gantry may be needed to meet demand for services by patients in the Washington metropolitan area.

## **2. Accessibility:**

The Applicant maintains that admission policies and patient selection criteria for proton therapy will be based only on clinical considerations. All potential proton therapy patients meeting clinical selection criteria will be provided social and financial assistance and support to remove any barriers to obtaining services. MGUH is open 24 hours a day, seven days a week, however, proton therapy is an outpatient service that is scheduled with the patient in advance. The facility is planned to be opened 14 hours a day, Monday through Friday, and if needed will expand to weekend hours.

The Applicant states that the MGUH proton therapy program can be accessed through any one of the following ways:

- Upon the referrals from primary care physicians and oncologists;
- Self-directed referrals through the emergency department, outpatient clinics, or through several outpatient satellites including the Pediatric Mobile Clinic.

Patient's without personal physicians or other medical homes are assigned a hospital-based physician;

- Referrals from third party payers;
- The MedStar Georgetown University Hospital's Website; and
- Community education conferences given by the Lombardi Cancer Center.

According to the Applicant, MGUH is accessible by public transportation including bus routes, Georgetown University "GUTS" Bus System, and free shuttle service for patients, visitors, and families to and from the Dupont Circle and Rosslyn Metro stations. Additionally, van service is provided to remote office and parking sites operated by the Hospital. All shuttle services are ADA accessible and operate Monday through Friday. All vehicles with a disability tag are provided valet parking services at no additional cost beyond the standard parking rates.

The Applicant maintains that MGUH does not deny services based on any protected status, including age, race, ethnicity, color, religion, creed, culture, language, physical or mental disability, sex, sexual preference or orientation, national origin, legal status, prior hospitalization, diagnosis, prognosis, disability, gender identity or expression, or socioeconomic status or payer source. The Applicant adds that MGUH is committed to ensuring that uninsured patients within its service area who lack financial resources have access to medically necessary hospital services. If patients are unable to pay for medical care, have no other insurance options or sources of payment, including Medical Assistance, litigation or third-party liability, such patients qualify for free or reduced cost medically necessary care.

The Applicant states that the proton therapy center will be fully accessible and ADA-compliant. MGUH has also made provisions to assist patients with disabilities. Patients

with hearing-impairments requiring an inpatient stay or a visit to one of MGUH's many clinics will receive:

- In-person sign language interpreters for inpatients during their physician's rounds and all clinic visits;
- Video sign language interpretative services are available in many areas of the hospital and can be used when acceptable to patients;
- All inpatient rooms and waiting areas are equipped with closed captioned TVs; and
- Several other communication assistance devices are available upon request such as TTY/TTD devices, amplified telephone handsets, assistive listening devices, and call bells.

The Applicant maintains that interpreter services for both American Sign Language and over 175 spoken languages are available 24/7 to all patients and families for appointments, procedures, and hospital stays. Interpretation is provided by video and phone through the MedStar Interpreter Network and on-demand spoken and sign language interpretation system, which provides immediate access to qualified medical interpreters. There is no cost to patients or families for interpretation at the hospital.

While the Applicant generally meets the criteria and standards of accessibility, SHPDA staff believes that the Applicant should and can do more to provide cancer care services to the underserved areas of the District. SHPDA staff believes that the Applicant can help reduce the rates of cancer in the District if it would provide cancer screening and treatment services to underserved populations in the District. SHPDA staff, therefore, recommends that, as a condition to certificate of need approval, the Applicant shall be required to establish, operate, and maintain a cancer screening and treatment clinic in an underserved area of the District. In addition, in order to ensure that underserved,

uninsured, under insured and minority patients will have access to proton therapy, staff proposes that the Applicant be required to make arrangements with the D.C Primary Care Association, clinics, hospitals, and other entities to make sure that patients will have access to proton therapy services when they need the treatment.

I agree with the recommendations of staff. The Project Review Committee and the Statewide Health Coordinating Council have also strongly endorsed the recommendation that the Applicant be required, as a condition of certificate of need approval, to establish and operate a cancer screening and treatment clinic in an underserved area of the city. As the Applicant states, the incidence and prevalence of cancer in the District is very high. While the Applicant's current proposal is to treat patients after their cancer has progressed, there is a need to be much more proactive in the prevention and early detection of the disease. It is, therefore, crucial that the Applicant redouble its efforts to fight the disease throughout the continuum of care.

### **3. Quality:**

According to the Applicant MGUH is licensed by the D.C. Department of Health and accredited by the Joint Commission, the American College of Surgeons, the National Committee for Quality Assurance, and the Accreditation Council on Graduate Medical Education. The Hospital is a member of the American Hospital Association and the Council of Teaching Hospitals, a division of the Association of American Medical Colleges. The LCCC is designated a Comprehensive Cancer Center by NCI of the National Institutes of Health. The Applicant states that at the LCCC there is a multidisciplinary approach to ensure that each patient's plan of care is individualized and meets the needs of the patient/family.

The Applicant maintains that performance improvement is administered by the Board of Directors Quality, Safety, and Professional Affairs Committee (SPAC). Two committees reporting to the SPAC are the Quality and Safety Executive Committee and the Medical Executive Committee. The Committees are in charge of the following:

The Quality and Safety Executive Committee serves as the leadership for activities associated with achieving measured, reliable, system-wide quality performance across all dimensions of care and service. The Committee promotes a culture of organizational improvement and patient safety and oversees the evaluation and implementation of system changes designed to achieve excellence in patient care and services. The responsibilities include:

- Prioritize organizational improvement activities to be aligned with strategic initiatives and focus on improving organizational performance and patient safety;
- Oversee improvement activities through review of reports and approval of recommendations from efforts focused on departmental performance improvement; patient physician and employee satisfaction; patient, employee and environmental safety; and regulatory compliance;
- Provide the resources and systems support necessary to assure success in the implementation of improvement strategies as well as efforts towards risk reduction and risk prevention;
- Review results of action plans and follow up of Performance Improvement activities and the findings of all Root Cause and Failure Mode and Effects Analyses to assure the processes have been thorough, that the appropriate staff have been assigned accountability for action items, and that any barriers to successful implementation have been addressed;
- Review of suits and claims to determine whether the care provided met the standards of care and if the case identifies any system issues related to either a clinical service or the Hospital as a whole; and
- Annual review of the Quality and Patient Safety improvement Plan, Sentinel Event follow-up, and Environment of Care Management Plans to assure that the

processes are meeting the objectives and are in compliance with the most recent standards of external accrediting or licensure agencies.

In case of a significant adverse event or near miss, as declared by the President or other designated party, an ad hoc group of members of the Committee will meet to:

- Conduct a thorough and credible root cause analysis under the auspices of peer review or systems review per the Sentinel Event Policy; and
- Report an accurate timeline of events and recommendations to decrease the likelihood that a similar event would occur.

The Medical Executive Committee is responsible for creating, implementing and overseeing several activities and peer review committees. Activities include comprehensive reports from each of the clinical services that address case review, quality indicators and performance improvement activities in the department. The Committee's responsibilities include:

- Review clinical departments' performance improvement/practice committee activities and trends with respect to clinical outcomes, quality improvement, risk management, and utilization management;
- Ensure standards of care for all patients through promotion of the use of evidenced based practice;
- Review and recommend changes to hospital standard practices, policies, and procedures that impact clinical care on behalf of the Medical Staff;
- Review the activities of Hospital and Medical Staff Standing Committees, as they relate to clinical practice, to assure coordination, implementation, and



communication of activities related to those required functions that cross multiple disciplines and patient types;

- Function as the approval body for any medical staff for recommendations from the following committees: Infection Prevention, Pharmacy and Therapeutics, Pain and Sedation, Blood Utilization Review Committee, Clinical Ethics, Cancer Committee, Center for Patient Safety, Compliance, CPR, Emergency Preparedness, Medical Records, Organ Donation, OR Safety, and Radiation Safety;
- Oversee a program of concurrent review of admissions and continued stay in accordance with applicable criteria, standards, and regulations; and
- Monitor the effectiveness of patient flow/discharge planning activities to assure an appropriate and timely level of care across the continuum.

The Applicant maintains that MGUH has a learning network that administers mandatory annual training requirements and continuing courses to ensure that staff are trained to care for patients. The standards for nursing education are high at MGUH and a clinical ladder has been developed with educational milestones. The Hospital has received accreditation from the Accreditation Council for Continuing Medical Education by offering a myriad of continuing medical education offerings.

Additionally, a parallel system has been established to train volunteers to be effective and productive members of the health care team.

The Applicant states that the FDA-approved Mevion S-250 was designed to be a practical medical device, with a modern design that is less complex, more reliable, easier to run, and far less expensive to operate. The Mevion modular treatment room design supports easy integration into existing facilities with minimized capital outlays, maximized deployment options, greater architectural flexibility, higher facility uptime, and lower operating costs compared to the larger multi-gantry systems. The Applicant

maintains that the Mevion S-250 proton therapy system provides the same precise, noninvasive treatment capabilities of other proton therapy units currently under clinical operation in the US. The major difference is that it does it in a significantly reduced footprint, and at a lower capital and operational cost. Additionally, the Mevion S-250 treatment process is guided by imaging technology and is completely integrated within the existing MGUH information system.

After a careful review of the information included in the record, staff believes, and I agree, that the Applicant has demonstrated the ability to provide quality care to patients seeking proton therapy services at MGUH.

#### **4. Continuity:**

The Applicant states that MGUH is a part of the MedStar Health System, an integrated health care delivery system with a comprehensive range of health care facilities in the District and the surrounding area, including primary, secondary, and tertiary level services. MGUH has referral linkages with its sister facilities and abides by transfer and coordination agreements with other health care providers. Procedures and protocols are in place to refer patients to the most appropriate site for care as is medically necessary. MGUH maintains that it has proper transfer mechanisms in place if it is determined that a patient would be more appropriately treated at another facility. In turn, MGUH accepts referrals of patients for consideration of radiation therapy treatment, which may include brachytherapy, IMRT, stereotactic radiosurgery, and CyberKnife. MGUH's Department of Case Management maintains linkages with various Washington metropolitan region human services agencies and community resources for referral and support services for discharged patients.

According to the Applicant, MGUH has in place all the necessary support services for a successful oncology program. The LCCC is an NCI designated cancer center that provides support and ancillary services such as:

- Social services and case management;
- Psychological support services;
- Pharmacotherapy and laboratory services;
- Physical therapy/fitness consultation;
- Nutrition and diet management;
- Pastoral care;
- Palliative care; and
- Pediatric services.

Based on the above information, I have concluded that MGUH is consistent with the criteria and standards of continuity of care.

#### **5. Acceptability:**

The Applicant maintains that MGUH provides patients/family members/visitors the opportunity to express concerns about issues or questions that may arise during their time in the Hospital. The Hospital patient complaint policy outlines the grievance process for patients and caregivers and is outlined in the patient handbook. Patient complaints and compliment correspondence are to be answered in a quick timeframe and monitoring is done to ensure appropriate adherence to the timelines. A patient care phone line for patients and visitors provides access to the Patient and Physician Advocacy Staff and the Privacy Liaison. Information about this service is posted in patient rooms, exam rooms, and waiting rooms, and in the patient handbook. The Applicant states that detailed policies and procedures for handling complaints and grievances are provided to all MGUH staff.

According to the Applicant, MGUH strives to ensure high satisfaction with services offered by the Hospital, through comprehensive, qualitative, and quantitative assessments of physician, employee, and consumer perceptions of their experiences with the care and services they received. Satisfaction data are reviewed by senior

management and the Board of Directors to identify opportunities for improving and enhancing services offered. The following assessments tools are utilized:

- Performance/experience survey;
- Patient satisfaction survey;
- Physician satisfaction survey; and
- Employee satisfaction survey.

The Applicant states that MGUH has received the following recognitions:

- U.S. News & World Report - Ranked as high performing hospital for cancer, diabetes, endocrinology, geriatrics, gynecology, nephrology, neurosurgery, orthopedics, pulmonology, and urology (2012);
- National Cancer Institute-Designated Comprehensive Cancer Center;
- American College of Radiology Designated Breast Center of Excellence;
- National Parkinson Foundation Center of Excellence;
- American College of Radiology Accredited for CT, Mammography, PET, Nuclear Medicine; and
- American Heart Association/American Stroke Association's Get with the Guidelines Stroke Silver Plus Quality Achievement Award.

According to the Applicant, the Hospital on a regular basis meets with consumer groups, including its Advisory Neighborhood Commission (ANC) and its Community Relations Council, in order to discuss the concerns and needs of the community and to share the Hospital's goals and plans. Notification of this project has been provided to ANC 2-E. The Applicant has provided a letter of support from ANC 2-E and has also

provided letters of support from Children's National Medical Center, Howard University, several physicians, the Federal City Council, and DC Councilmembers.

At the public hearing that was held on January 8, 2013, the Applicant and members of the public provided testimony regarding the proposed project. Several physicians spoke in support of the establishment of proton therapy at Georgetown. Dr. Atkins said that it will be useful to patients, will improve the clinical capabilities at Georgetown, and will promote research. Dr. Batipps stated that proton therapy is precise and reduces the possibility of toxicity. He also said that the facility is a teaching hospital with a research program that will benefit from the technology. Dr. Collins discussed the usefulness of stereotactic radio therapy and how it has improved over time. He noted that they treat many patients and that the proposed unit will be a useful addition.

Similarly, Mr. Kevin Wrege said that his wife is a two-time cancer survivor who received great care at Georgetown. He said that the Hospital treats the whole patient and provides holistic care. Mr. Solomon, an ANC 2E Commissioner, said that he supports many residents in their decision to go to the LCCC, and he receives a great deal of positive feedback about the services. He continued to say that it is important that the community has access to the most advanced cancer treatment that is available. He also noted that his ANC is highly supportive of the project.

Based on the above, I have determined that MGUH is consistent with the criteria and standards for the acceptability of care.

**6. Financial Feasibility:**

The Applicant states that the proposed capital expenditure for this project is \$32,089,000 and the project is scheduled to be completed in 2014. The Applicant states that the proton therapy center will be constructed as an addition to the existing LCCC. The capital project consists of approximately \$22 million for the purchase of the equipment, \$8 million in construction and renovation, \$1.2 million in pre-development

costs, and \$840,000 in contingency and education costs. The Applicant has stated that it will fund the project through retained earnings and has the cash in hand to finance the project. The Applicant states that MedStar currently holds approximately \$1.3 billion in unrestricted cash and investable assets, which would be used to fund the project. The Applicant states that the Board of Directors of MedStar Health, Inc. has concluded that:

1. MedStar Health, Inc. is the sole member of MedStar-Georgetown Medical Center, Inc., d/b/a MedStar Georgetown University Hospital (the "Hospital"), and as such has reserved authority to approve capital budgets and projects for the Hospital.
2. MedStar Health, Inc.'s Board reviewed and approved the Hospital's proton beam therapy project at a duly called meeting of the Board of Directors on September 19, 2012.

The Applicant states that MedStar generally funds major capital projects with a combination of operating cash, new debt, and philanthropy. Additionally, the Applicant states that if MedStar decided to refinance the capital costs, it has an A2 credit rating from Moody's Investors Service, an A- rating from Standard and Poor's and an A rating from Fitch Ratings . The Applicant maintains that at these rating levels, it can be expected that there will be sufficient investor interest in a tax-exempt debt financing for this project should MedStar choose to refinance the project in the future.

The Applicant maintains that the average cost per treatment is approximately \$1,700. Since the Applicant indicates that a patient would need about 28 treatments, the total treatment cost is estimated at approximately \$48,000 (1700 x 28).

Based on the above information, I have determined that MGUH is consistent with the criteria and standards for financial feasibility.

**C. Compliance with Uncompensated Care Requirements:**

The Applicant has reiterated its commitment to provide uncompensated care to needy patients. I am, therefore, satisfied that the Applicant is consistent with the requirements.

**D. Conclusion:**

After a careful review of the application, the staff report, the recommendations of the Project Review Committee and the Statewide Health Coordinating Council, and the full record, I have determined that the Applicant has demonstrated the need for the establishment of proton therapy services. Proton therapy services will provide an alternative treatment modality for cancer patients. While it is true that the effectiveness of the modality is not definitive, the technology has a huge potential for controlling the dose of radiation and minimizing damage to surrounding tissue and/or organs. I also believe that as an academic, teaching, and research facility, the Hospital has demonstrated the need to establish the services to help train medical students and fellows as well as to participate in clinical trials and research on the utilization and effectiveness of the modality. In short, as a leading academic medical center, it is necessary the MGUH be equipped with the most cutting-edge, state-of-the-art technology for cancer treatment and research. The availability of the services will ensure that residents will have access to needed services close to home. It is burdensome on patients and families to travel to other cities given the need for multiple treatments.

The 308 patients that MGUH projects to serve are primarily to be generated from its patient base. MGUH also states that these patients will account for over 80% of the capacity. While the Applicant maintains that the District does not need more than one proton facility, it is not clear how patients from other facilities, including those in the MedStar Health Cancer Network, will be able to fully access the services. During the public hearing the Applicant stated that services may also be provided on Saturdays to add capacity to the facility. But even then only about 70 patients could be added to the

capacity. In short, the Applicant has not demonstrated that the unit can provide over 12,500 treatments a year, and leaves little room for referrals from other facilities to access the services.

Staff has also determined that the Applicant has demonstrated that it has the capability to provide quality care to patients seeking proton therapy services. Additionally, the Applicant has provided information to show that it has the support of its Board of Directors to finance the project and that the project should generate more revenues than expenses.

One of the down sides of proton therapy is that it is very expensive to acquire and operate. The technology costs tens of millions of dollars, or 20 to 30 times more than existing technology. The operation of a proton facility also requires highly trained medical and technical staff. In addition to the clinical staff, the operation must have a team of physicists and engineers to maintain and operate the particle accelerator. The space requirements are also very huge. Some argue that the opportunity cost of the resources required makes the establishment of a proton facility unsupportable. It is said that the millions of dollars that are needed to establish a facility that treats relatively few patients are not justified, and that it would be more prudent to spend the resources in early intervention efforts to prevent cancer. It is also pointed out that all the money is spent on a technology whose efficacy has not been clearly demonstrated.

What is clear, however, is that proton therapy is an evolving technology and that there is a need for continued research to refine and improve the usefulness and applicability of the procedure. It is, therefore, important to have the service established in institutions that have the clinical, research and educational components and are in a position to move the technology forward through appropriate clinical trials and biologic and DNA research.

While it is true that the SHPDA must work to keep health care costs down, it must be balanced with efforts to ensure that the medical innovation and access to cutting-edge



treatment are not stifled. Medicine can advance only when clinicians, hospitals, and research institutions undertake rigorous clinical trials. I, therefore, believe that the establishment of the service will not only provide treatment to patients whose tumors are not amenable to conventional radiation, but will help advance research to control the disease and provide education and training to health care professionals and medical students.

According to the District of Columbia Cancer Report 2011, approximately 8,200 new cases are added annually to the District's cancer registry. Of these approximately 3,100 are District residents. Cancer is the number one cause of premature deaths, far greater than heart disease, HIV/AIDS, homicide/assault and accidents. The most common cancers in the District are breast, lung and bronchus, prostate and colorectal.

The diagnosis of cancer at an early stage is known to increase the likelihood of successful treatment. As a result, detecting cancer early through regular screening is the most effective way of identifying cancer when it is most treatable. The literature indicates that programs that improve access to care through patient navigation and community education, particularly among underserved populations, have a greater chance of preventing and detecting cancer. It is, therefore, crucial that the Applicant establish programs to increase cancer awareness and help reduce the incidence and prevalence of cancer in the city. Such programs will help ensure timely and proper diagnosis and follow-up care. It is also very important that screening programs be expanded beyond breast cancer and include, at a minimum, lung, prostate, and colorectal cancers. The higher overall cancer incidence among Black District residents is attributed to a higher incidence of these cancers. The SHPDA understands and appreciates that the Hospital currently provides a number of services in the community to address cancer health disparities. What the SHPDA is now proposing is that the Hospital establish a clinic specifically dedicated to cancer and to provide outreach, educational, screening, navigation, and treatment services.

Cancer mortality is highest in areas of the District which have large concentrations of African-American, Hispanic, and low-income residents. The higher overall cancer incidence among black District residents is attributable to a higher incidence of colorectal, lung and prostate cancers. The problem is compounded by the fact that many residents do not have the knowledge or financial means to seek and receive medical care before their cancers progress. It is reported that newly diagnosed cancer patients in the District are more than twice as likely to seek care with Stage IV cancers if they are uninsured or underinsured. This is partly attributable to the fact that patients in underserved areas do not have ease of access to adequate screening to prevent and detect cancer. The problem is compounded by the fact that screening results are frequently not acted upon in a timely manner due to lack of follow up.

As a result, while efforts to cure and control the disease are important, there is a need to redouble efforts in the area of prevention and early detection. Education programs have to be developed to change the culture and encourage residents to get checked, to seek help early and frequently, and to follow up when a problem is indicated. Screening tests are very important because they can help find cancer at an early stage, before symptoms appear, and when treatment is more effective and cure is possible. But since screening results may not lead to clear diagnosis by themselves, diagnostic tests are frequently required to establish a definitive diagnosis. As a result, it is crucial that uninsured and underinsured patients are given access not only to screening but also to follow up diagnosis and treatment.

In addition to a physical clinic for screening, evaluating and treating cancers in an underserved area of the District, the Applicant should propose and deploy an educational program for the underserved population in which fear of cancer and distrust of the medical establishment is a known barrier to seeking care. Lack of understanding of the importance of early detection, and poor knowledge of modern cancer treatment continues to contribute to poor outcomes for District residents. The Applicant should design and deploy a cost-effective, community-based education program as well as

providing an annual summary documenting its effectiveness in terms of citizen contact and, ideally, changes in behavior.

It must also not be forgotten that establishing a clinic in an underserved community will benefit the teaching programs of the Applicant. Exposure to an additional large population of patients, some with challenging medical and oncological conditions, will likely enhance post-graduate training of fellows and residents. Such a clinic will also benefit the District more broadly by helping to diminish the perception of a health care divide between the various wards of the city.

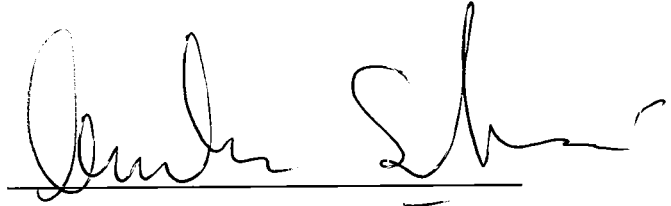
I have, therefore, determined that MedStar Health, Inc./MedStar Georgetown University Hospital be approved for the establishment of a one-gantry proton therapy service. I have further determined that, as a condition of certificate of need approval, the Applicant shall be required to address some of the disparities in cancer education, screening, and treatment in the District, particularly access to services by underserved residents as follows:

- Given the incidence and prevalence of cancer in the District of Columbia and given the health disparities in the city, the Applicant shall, in consultation with the Department of Health, establish, operate and maintain a full time new cancer screening and treatment clinic in one of the underserved areas of the District in Ward 5 or 7, particularly to prevent and treat the most common cancers – breast, lung, prostate and colorectal - and provide a clear plan of implementation with its second quarterly progress report;
- In order to ensure that underserved, uninsured, underinsured, and minority patients have access to proton therapy treatment, the Applicant must enter into clear arrangements with the D.C. Primary Care Association, clinics, hospitals, and other entities that serve these patients and establish mechanisms to facilitate access to the proton therapy services and report to the SHPDA with its first year progress report; and

- Provide to SHPDA annually information on the proton therapy utilization and on the operations of the cancer screening and treatment clinic, including the number of patients served, the diagnosis, source of payment, source of referral, as well as the race, age, sex, ward, and zip code of the patients.

May 31, 2013

Date

A handwritten signature in black ink, appearing to read 'Amha W. Selassie', written over a horizontal line.

Amha W. Selassie  
Director